IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)
Plaintiff,)
V.)
SAREPTA THERAPEUTICS, INC.,)
Defendant.)) _) C.A. No. 21-1015-JLH
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA,)))
Counter-Plaintiffs,)
v.)
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC.,)))
Counter-Defendants.)) _)

ORDER AFTER PRETRIAL CONFERENCE

At Wilmington, this 11th day of December 2024, upon consideration of the parties' Amended Joint Proposed Pretrial Order (D.I. 646), and for the reasons extensively discussed at the December 9, 2024 Pretrial Conference ("Tr. __"), IT IS HEREBY ORDERED that:

1. The Proposed Amended Joint Pretrial Order (D.I. 646) will be ADOPTED as modified by this order and any discussions at the December 9, 2024 Pretrial Conference. The parties should consult the transcript of the Pretrial Conference for a full understanding of the Court's rulings.

- 2. The Court heard argument on Sarepta's "Motion (#1) to Exclude NS's Expert Opinions and Testimony Applying a New and Improper Construction of 'Morpholino.'" (D.I. 607; Tr. 12–24.) The motion was DENIED to the extent that it sought to preclude certain testimony by NS's experts. However, it became apparent at the Pretrial Conference that the parties have a dispute about the meaning of the term "morpholino" (which the Court was not previously asked to construe), and the parties agree that the Court (not the jury) should resolve that dispute. As discussed at the Pretrial Conference, the Court has determined that the best course of action under the circumstances is for the Court to make a decision about the proper construction of "morpholino" at the charge conference so that the jury can be instructed appropriately. Accordingly, the parties should be prepared to offer their proposed constructions at the charge conference.
- 3. Sarepta's "Motion (#2) to Exclude Dr. Matthew J.A. Wood's Irrelevant and Unhelpful Opinions and Testimony" (D.I. 608) was DENIED. (Tr. 25–38.) Sarepta's "Motion (#3) to Exclude Dr. Michelle L. Hastings's Opinions and Testimony Concerning Enablement of 5'- and 3'-End Modifications" (D.I. 609) was DENIED. (Tr. 38–45.) Sarepta's "Motion (#4) to Exclude Dr. Michelle L. Hastings's Opinions and Testimony Applying Incorrect Written Description Law" (D.I. 610) was GRANTED-IN-PART and DENIED-IN-PART. (Tr. 45–57.) The parties will be held to their representations at the Pretrial Conference, and the parties should consult the transcript for a full understanding of the Court's rulings.
- 4. NS's "Motion to Exclude Opinions of Dr. Steven Dowdy, Ph.D." (D.I. 613) was DENIED. (Tr. 57.)
- 5. The Court heard argument on NS's "Motion to Strike Certain Supplemental Opinions from Sarepta's Economic Expert John Jarosz" (D.I. 640) and NS's May 7, 2024 letter.

- (D.I. 568; Tr. 57–73, 131–133.) The Court requested further briefing, which has been provided (D.I. 665), and the Court has the matter under advisement.
- 6. Sarepta's Motion in Limine No. 1 (D.I. 536, Ex. 18) was GRANTED-IN-PART and DENIED-IN-PART. (Tr. 73–85.) The parties should consult the transcript for a full understanding of the Court's ruling.
- 7. The parties reached agreement on Sarepta's Motion in Limine No. 2 (D.I. 536, Ex. 19; Tr. 85–90), Sarepta's Motion in Limine No. 3 (D.I. 536, Ex. 20; D.I. 646 ¶ 76), and NS's Motion in Limine No. 3 (D.I. 536, Ex. 17; Tr. 4–5). The parties will be held to their agreements and representations in the Amended Pretrial Order and at the Pretrial Conference.
- 8. The Court heard argument on Sarepta's request that NS be permitted to assert only one patent claim. (D.I. 646 ¶ 84; Tr. 91–98.) The Court requested further briefing, which has been provided. (D.I. 665.) Under these unique circumstances—*i.e.*, where both sides have stipulated to infringement of the other side's patent(s), where Sarepta is only asserting one claim and NS is asserting three (down from the five they were asserting prior to the Pretrial Conference), where Sarepta contends (and NS does not dispute) that both sides and their experts have treated all of NS's asserted claims interchangeably for purposes of both validity and damages, where NS was unable at the Pretrial Conference to articulate a material difference between any of the asserted claims, where the parties' proposed verdict forms require Sarepta to prove that all of NS's asserted patent claims are invalid in order to avoid paying damages, and where Sarepta has offered to stipulate that the jury verdict as to one asserted patent claim will be applicable to the other two claims—the Court has determined as follows: NS shall not be required to reduce the number of asserted claims. However, to account for the fact that Sarepta will have to prove invalidity of three claims, the Court will shift 30 minutes of the jury trial time to Sarepta, *i.e.*, NS shall receive 11.5

hours, and Sarepta shall receive 12.5 hours. If NS reduces the asserted claims to one claim by 5:00 P.M. on December 13, 2024, the parties will receive an equal amount of trial time.

- 9. At the Pretrial Conference, Sarepta's counsel raised for the first time a potential issue concerning the proposed verdict forms submitted by the parties. (Tr. 7–12.) The issue has to do with the fact that the parties' proposed verdict forms ask the jury to award lost profits to both sides if the jury finds that both sides' patents are valid. The Court requested further briefing, which has been provided (D.I. 665), and has the parties' proposal(s) under advisement. The Court is also considering whether, under these unusual circumstances, the most appropriate course of action would be to phase the issues of liability and damages, with the idea that both would still be tried next week to the same jury.
- 10. The Court heard argument on the parties' dispute about interpreters. (Tr. 101–108.) The Court requested further briefing, which has been provided. (D.I. 665.) Mr. Paul Hersey shall serve as the interpreter for trial, at NS's expense. NS may meet with Mr. Hersey to prepare its witnesses prior to trial. Sarepta may bring a check interpreter to trial. Sarepta may use its own interpreter or Mr. Hersey for its cross-examination. The parties shall meet and confer and attempt to reach agreement on "freezing" Mr. Hersey at a reasonable time prior to his services at trial if Sarepta would like to meet with him (at Sarepta's expense).
- 11. The Court ordered that Donald Foy will be permitted to testify. (Tr. 115–121.) The parties will be held to their representations at the Pretrial Conference, and the parties should consult the transcript for a full understanding of the Court's rulings.

¹ The parties have stipulated to infringement of each other's patents.

12. The parties raised a new dispute about Mr. Hosfield's testimony. (D.I. 665.) NS

has offered to "limit itself to four damages scenarios" by December 13, 2024, at 5:00 P.M. NS is

ordered to do so.

13. Jury selection by a Magistrate Judge will occur on December 13, 2024. The Court

intends to read the preliminary jury instructions on December 13 after the jury is selected. Opening

statements will begin on December 16, 2024, at 9:00 A.M. Each party should be prepared to

present its case to the jury until at least 5:00 P.M. of each trial day. Trial counsel must be present

and ready to proceed at 8:30 A.M. on December 16, 2024, and on each and every day of trial

thereafter. Subject to Paragraph 8 above, each side will have 12 hours for opening statements,

presentation of evidence, and closing arguments. Each side must reserve at least one hour for

closing arguments.

14. The bench trial will occur the week of December 16, 2024, in the evenings and/or

while the jury is deliberating. Each side will have 2.25 hours for its presentation. The parties

recently provided competing proposals for the sequencing of the bench trial (D.I. 665), and the

Court has the dispute under advisement.

The Honorable Jennifer L. Hall

UNITED STATED DISTRICT JUDGE